

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

SLATER et al.

Serial No. 10/537,543

Filed: June 3, 2005

For: HYPERCOILING POLYMERS AND THEIR USE IN
CELLULAR DELIVERY

Atty. Ref.: 620-366

Group: Unassigned

Examiner: Unassigned

* * * * *

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

July 20, 2005

Sir:

INFORMATION DISCLOSURE STATEMENT

- ☒ 1. **PTO-1449 Pursuant to 37 CFR 1.97(b)**
[within 3 months of filing or prior to 1st Office Action on the merits]
N/C
- ☐ 2.(a) **Statement Pursuant to 37 CFR 1.97(c)**
[before Final Office Action or Allowance (requires Rule 97(e)
Statement or Rule 17(p) fee)]
N/C
- ☐ 2.(b) **Fee Payment Pursuant to 37 CFR 1.97(c)**
[before Final Office Action or Allowance (requires Rule 97(e)
Statement or Rule 17(p) fee)]
\$180.00
- ☐ 3. **Pursuant to 37 CFR 1.97(d)**
[after Final Office Action or Allowance (requires Rule 97(e)
Statement and Rule 17(p) fee), but before final fee payment]
\$180.00

The following are submitted in the above-identified application in compliance with 37 C.F.R. §§ 1.97 and 1.98:

- ☒ 4. A list of documents on Form PTO-1449 together with copies of each identified document and a translation or a concise explanation of each non-English language document (such as a Search Report) is enclosed herewith.

This paper is submitted in accordance with:

- ☒ 5. 37 CFR 1.97(b): [within 3 months of filing or prior to 1st Office Action]
- ☐ 6. 37 CFR 1.97(c): [before Final Office Action or Allowance, whichever is earlier]; and
- ☐ a) The required Statement made in item 8 below; or
- ☐ b) The \$180.00 fee specified in 37 CFR §1.17(p) for submission of this Information Disclosure Statement is authorized in item 9 below.
- ☐ 7. 37 CFR §1.97(d): [after Final Office Action or Allowance (requires Rule 97(e) Statement and Rule 17(p) fee), but before final fee payment]; and
- ☐ a) The fee (\$180.00) required by 37 CFR §1.17(p) is submitted herewith; and
- ☐ b) The required Statement is stated in item 8 below.
- ☐ 8. Statement under 37 CFR 1.97(e)
- ☐ a) The undersigned attorney of record hereby certifies under 37 C.F.R. §1.97(e) that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement (each item contained in this IDS was the first citation of that item by a foreign patent office in a counterpart foreign application which occurred no more than three months prior to the filing of this IDS); or
- ☐ b) No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement, after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

SLATER et al.
Serial No. 10/537,543

- ☒ 9. Please charge all deficiency fees associated with the submission of this Information Disclosure Statement and any other fees applicable to this application to Deposit Account No. 14-1140. An original and one (1) copy of this document are enclosed.

Respectfully submitted,
NIXON & VANDERHYE P.C.

By: _____



B. J. Sadoff
Reg. No. 36,663

901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100

**INFORMATION DISCLOSURE
CITATION**

ATTY. DOCKET NO.

SERIAL NO.

620-366

10/537,543

APPLICANT

SLATER et al.

(Use several sheets if necessary)

FILING DATE

GROUP

June 3, 2005

Unassigned

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,028,689	07/1991	Heinz et al.			
	5,948,878	09/1999	Burgess et al.			
	6,063,370	05/2000	Dadey			
	6,210,717	04/2001	Choi et al.			

FOREIGN PATENT DOCUMENTS

DOCUMENT		DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO 98/35688	08/1998	WIPO				
	WO 99/09955	03/1999	WIPO				
	WO 02/092554	11/2002	WIPO				
	EP 0 727 223 A1	08/1996	Europe				
	670 721	04/1952	Great Britain				
	WO 98/19710	05/1998	WIPO				
	WO 99/55743	11/1999	WIPO				
	WO 99/42091	08/1999	WIPO				
	WO 00/63409	10/2000	WIPO				

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

	Agi, Y., et al., 1997, "Fluorescence monitoring of the microenvironmental pH of highly charged polymers", <u>Journal of Polymer Science, Part A: Polymer Chemistry</u> , Vol. 35, pp. 2105-2110.
	Maeda, M., et al., 1988, "H ⁺ -induced release of contents of phosphatidylcholine vesicles bearing surface-bound polyelectrolyte chains", <u>J. Am. Chem. Soc.</u> , Vol. 110, pp. 7455-7459.
	Mandel et al., 1967, "The conformational transition of poly(methacrylic acid) in solution," <u>J. Phys. Chem.</u> , Vol. 71, No. 3, pp. 603-612.
	Marecos, E., et al., 1998, "Antibody-mediated versus nontargeted delivery in a human small cell lung carcinoma model," <u>Bioconjugate Chem.</u> , Vol. 9, No. 2, pp. 184-191.
	Matthews, S.E., et al., 1996, "Macromolecular systems for chemotherapy and magnetic resonance imaging", <u>Advanced Drug Delivery Reviews</u> , Vol. 18, pp. 219-267.
	Muller, G., 1974, "Electric permittivity of polyelectrolytes. I. Effect of ionization on the dielectric behaviour of a polycondensate between L-lysine and 1,3-benzene disulfonyl chloride", <u>Polymer Letters Edition</u> , Vol. 12, pp. 319-326.
	Mungara, P.M., et al., 1993, "Synthesis of polyamides containing dipeptide linkages," <u>Chem. Mater.</u> , Vol. 5, No. 9, pp. 1242-1246.
	Mungara, P.M., et al., 1994, "Chapter 11: Synthesis of Functionalized Targeted Polyamides," in <u>ACS Symp. Ser.</u> , Vol. 575, pp. 160-170.

*Examiner

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)

INFORMATION DISCLOSURE CITATION	ATTY. DOCKET NO.	SERIAL NO.
	620-366	10/537,543
(Use several sheets if necessary)	APPLICANT	
	SLATER et al.	
	FILING DATE	GROUP
	June 3, 2005	Unassigned

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

	Murthy, N., et al., 1999, "The design and synthesis of polymers for eukaryotic membrane disruption," <u>J. Controlled Release</u> , Vol. 61, pp. 137-143.
	Nagasawa, M., 1971, "Potentiometric titration and conformation of synthetic and natural polyelectrolytes," <u>Pure Appl. Chem.</u> , Vol. 26, Nos. 3-4, pp. 519-536.
	Ohno, N., et al., 1973, "Conformational transition of the copolymer of maleic acid and styrene in aqueous solutions," <u>J. Polymer Science: Polymer Physics Edition</u> , Vol. 11, pp. 413-425.
	Ostolaza, H., et al., 1997, "Balance of electrostatic and hydrophobic interactions in the lysis of model membranes by <i>E. coli</i> α -haemolysin," <u>J. Membrane Biol.</u> , Vol. 158, pp. 137-145.
	Parkhe, A.D., et al., 1998, "Effect of local sequence inversions on the crystalline antiparallel β -sheet lamellar structures of periodic polypeptides: implications for chain-folding", <u>International Journal of Biological Macromolecules</u> , Vol. 23, pp. 251-258.
	Pichon, C., et al., 2001, "Histidine-rich peptides and polymers for nucleic acids delivery", <u>Advanced Drug Delivery Reviews</u> , Vol. 53, pp. 75-94.
	Plank, C., et al., 1995, "The influence of endosome-disruptive peptides on gene transfer using synthetic virus-like gene transfer systems," <u>J. Biol. Chem.</u> , Vol. 269, pp. 12918-12924.
	Pokhrel, M.R., et al., 2000, "Synthesis, characterization, and first application of high molecular weight polyacrylic acid derivatives possessing perfluorinated side chains and chemically linked pyrene labels", <u>J. Phys. Chem. B.</u> , Vol. 104, pp. 2215-2223.
	Reddington, M.V., 1998, "New glycoconjugated cyanine dyes as fluorescence labelling reagents," <u>J. Chem. Soc., Perkin Trans.</u> , Vol. 1, pp. 143-147.
	Amiji, M.M., et al., 2001, "pH-Responsive Polymer Microspheres: Rapid Release of Encapsulated Material Within the Range of Intracellular pH", <u>Angewandte Chemie International</u> , Vol. 40, pp. 1707-1710.
	Angelova, N., et al., 1999, "Rationalizing the design of polymeric biomaterials," <u>TIBTECH</u> , October 1999, Vol. 17, pp. 409-421.
	Anghel, D.F., et al., 1998, "Fluorescent dyes as model 'hydrophobic modifiers' of polyelectrolytes: a study of poly(acrylic acid)s labelled with pyrenyl and naphthyl groups," <u>Polymer</u> , Vol. 39, No. 14, pp. 3035-3044.
	Anufrieva, E.V., et al., 1968, "The models of denaturation of globular proteins. II. Hydrophobic interactions and conformational transition in polymethacrylic acid," <u>J. Polymer Science: Part C</u> , No. 16, pp. 3519-3531.
	Hoffman, A.S., et al., 2000, "Really smart bioconjugates of smart polymers and receptor proteins," <u>Smart Bioconjugates</u> (Founder's Award, Sixth World Biomaterials Congress 2000, Kamuela, HI, May 15-20, 2000), pp. 577-586.
	Huguet, J., et al., 1991, "Hydrosoluble polymeric drug carriers derived from citric acid and L-lysine", <u>American Chemical Society</u> , pp. 407-417.

Examiner	Date Considered
----------	-----------------

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)

**INFORMATION DISCLOSURE
CITATION**

ATTY. DOCKET NO.

SERIAL NO.

620-366

10/537,543

APPLICANT

SLATER et al.

(Use several sheets if necessary)

FILING DATE

GROUP

June 3, 2005

Unassigned

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

	Jensen, K.D., et al., 2001, "The cytoplasmic escape and nuclear accumulation of endocytosed and microinjected HPMA copolymers and a basic kinetic study in Hep G2 cells," <u>American Association of Pharmaceutical Scientists</u> , Vol. 3, No. 4, Article 32, pp. 1-14.
	Jones, G., et al., 2001, "Azole-linked coumarin dyes as fluorescence probes of domain-forming polymers", <u>Journal of Photochemistry and Photobiology B: Biology</u> , Vol. 65, pp. 5-12.
	Jones, G., et al., 1994, "Fluorescence properties of coumarin laser dyes in aqueous polymer media. Chromophore isolation in poly(methacrylic acid) hypercoils", <u>Journal of Physical Chemistry</u> , Vol. 98, No. 49, pp. 13028-13037.
	Klick, K.L., et al., 2000, "Protein engineering by in vivo incorporation of non-natural amino acids: control of incorporation of methionine analogues by methionyl-tRNA synthetase", <u>Tetrahedron</u> , Vol. 56, pp. 9487-9493.
	Klick, K.L., et al., 2001, "Identification of an expanded set of translationally active methionine analogues in <i>Escherichia coli</i> ", <u>FEBS Letters</u> , Vol. 502, pp. 25-30.
	Kimoto, A., et al., 1992, "Antitumor effects of SMANCS on rat mammary tumor induced by 7,12-dimethylbenz[a]anthracene," <u>Cancer Research</u> , Vol. 52, pp. 1013-1017.
	Kitano, H., et al., 1991, "pH-responsive liposomes which contain amphiphiles prepared by using lipophilic radical initiator", <u>Macromolecules</u> , Vol. 24, pp. 42-46
	Kost, J., et al., 1991, "Responsive polymeric delivery systems", <u>Advanced Drug Delivery Reviews</u> , Vol. 6, pp. 19-50.
	Kumar, M.N.V.R., 2000, "Nano and microparticles as controlled drug delivery devices", <u>J. Pharm. Pharmaceut. Sci.</u> , Vol. 3, pp. 234-258.
	Lackey, C.A., et al., 1999, "Hemolytic activity of pH-responsive polymer-streptavidin bioconjugates", <u>Bioconjugate Chem.</u> , Vol. 10, pp. 401-405.
	Langer, R., 1990, "New Methods of Drug Delivery", <u>Science</u> , Vol. 249, pp. 1527-1531.
	Leyte, J.C. and Mandel, M., 1964, "Potentiometric Behaviour of Polymethacrylic acid", <u>J. Poly. Sci. Part. A</u> , Vol. 2, pp. 1879-1891.
	Li, C., et al., 1989, "Synthesis of poly(iminocarbonates): degradable polymers with potential applications as disposable plastics and as biomaterials," <u>Macromolecules</u> , Vol. 22, No. 5, pp. 2029-2036.
	Reddington, M.V., 1998, "New glycosylated cyanine dyes as fluorescent labeling reagents," <u>J. Chem. Soc., Perkin Trans. 1</u> , pp. 143-148.
	Rihova, B., et al., 2001, "Doxorubicin bound to a HPMA copolymer carrier through hydrazone bond is effective also in a cancer cell line with a limited content of lysosomes," <u>J. Control. Rel.</u> , Vol. 74, pp. 225-232.
	Ringsdorf, H., 1975, "Structure and properties of pharmacologically active polymers," <u>J. Polymer Science: Symposium No. 51</u> , pp. 135-153.

*Examiner

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)

INFORMATION DISCLOSURE CITATION	ATTY. DOCKET NO.	SERIAL NO.
	620-366	10/537,543
(Use several sheets if necessary)	APPLICANT	
	SLATER et al.	
	FILING DATE	GROUP
	June 3, 2005	Unassigned

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

	Rösler, A., et al., 2001, "Advanced drug delivery devices via self-assembly of amphiphilic block copolymers", <u>Advanced Drug Delivery Reviews</u> , Vol. 53, pp. 95-108
	Rutkaite R., et al., 2001, "Fluorescence properties of carbazoyl-containing amphiphilic polymers," <u>J. Photochem. Photobiol. A: Chem.</u> , Vol. 138, pp. 245-251.
	Saotome, K., et al., 1967, "Optically active polyamides with regular structural sequences prepared from α -amino acid," <u>Die Makromolekulare Chemie</u> , Vol. 109, pp. 239-248.
	Seymour, L.W., et al., 1995, "Influence of molecular weight on passive tumour accumulation of a soluble macromolecular drug carrier," <u>European Journal of Cancer</u> , Vol. 31A, No. 5, pp. 766-770.
	Styring et al., 1989, in: <u>Determination of Molecular Weight</u> , Cooper AR, editor (Wiley, New York), pp. 263-300.
	Sugai, S., et al., 1986, "Conformations of Hydrophobic Polyelectrolytes", <u>Advances in Colloid and Interface Science</u> , Vol. 24, pp. 247-282.
	Taillefer, J., et al., 2001, "In-vitro and in-vivo evaluation of pH-responsive polymeric micelles in a photodynamic cancer therapy model", <u>Journal of Pharmacy and Pharmacology</u> , Vol. 53, No. 2, pp. 155-166.
	Thomas, J.L., et al., 1992, "Polyelectrolyte-sensitised phospholipid vesicles," <u>Acc. Chem. Res.</u> , Vol. 25, pp. 336-342.
	Thomas, J.L., et al., 1994, "Membrane solubilization by a hydrophobic polyelectrolyte: surface activity and membrane binding," <u>Biophysical Journal</u> , Vol. 67, pp. 1101-1106.
	Thomas, J.L., et al., 1996, "Modulation of mobilities of fluorescent membrane probes by adsorption of a hydrophobic polyelectrolyte," <u>Macromolecules</u> , Vol. 29, No. 7, pp. 2570-2576.
	Thomas, J.L., et al., 2000, "Polymer-induced leakage of cations from dioleoyl phosphatidylcholine and phosphatidylglycerol liposomes", <u>Journal of Controlled Release</u> , Vol. 67, pp. 203-209.
	Tirrell, J.G., et al., 1996, "Synthesis of biopolymers: proteins, polyesters, polysaccharides and polynucleotides," <u>Current Opinion in Solid State & Materials Science</u> , Vol. 1, pp. 407-411.
	Tonge, S.R., et al., 2001, "Responsive hydrophobically associating polymers: a review of structure and properties", <u>Advanced Drug Delivery Reviews</u> , Vol. 53, pp. 109-122.
	Tung, C-H., et al., 2000, "In-vivo imaging of proteolytic enzyme activity using a novel molecular reporter", <u>Cancer Research</u> , Vol. 60, pp. 4953-4958.
	Weissleder, R., et al., 1999, "In vivo imaging of tumours with protease-activated near infrared fluorescent probes," <u>Nature Biotechnology</u> , Vol. 17, pp. 375-378.
	Atkins, P.W., 1989, <u>Physical Chemistry</u> , third edition, (publisher: Oxford University Press), pp. 615-620.

*Examiner	Date Considered
-----------	-----------------

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)

**INFORMATION DISCLOSURE
CITATION**

ATTY. DOCKET NO.

SERIAL NO.

620-366

10/537,543

APPLICANT

SLATER et al.

(Use several sheets if necessary)

FILING DATE

GROUP

June 3, 2005

Unassigned

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

	Ballou, B., et al., 1997, "Tumour detection and cyanine visualisation using flurochrome-labeled antibodies," <u>Biotechnol. Progr.</u> , Vol. 13, pp. 649-658.
	Boudreaux, C.J., et al., 1997, "Controlled activity polymers. XI Hydrolytic release studies of hydrophilic copolymers with labile esters of model allelopathic phenols", <u>Journal of Controlled Release</u> , Vol. 44, pp. 185-194.
	Boustta, M., et al., 1991, "New functional polyamides derived from citric acid and L-lysine: synthesis and characterization," <u>Makromol. Chem. Macromol. Symp.</u> , Vol. 47, pp. 345-355.
	Chee, C.K., et al., 2001, "Fluorescence investigations of the thermally induced conformational transition of poly(<i>N</i> -isopropylacrylamide)", <u>Polymer</u> , Vol. 42, pp. 5079-5087.
	Coley M.C, Lewandowicz G, Sargent J.M and Verill M, 1997, "Chemosensitivity testing of fersh and continuous tumour cell cultures using lactate dehydrogenase," <u>Anticancer Research</u> , Vol. 17, pp. 231-236.
	Delaire, J.A., et al., 1984, "Quenching of fluorescence in water-soluble copolymers of methacrylic acid and vinylidiphenylanthracene," <u>J. Phys. Chem.</u> , Vol. 88, pp. 6219-6227.
	Domb, A.J., 1990, "Biodegradable polymers derived from amino acids," <u>Biomaterials</u> , Vol. 11, pp. 686-689.
	Doty, P., et al., 1957, "Polypeptides. VIII. Molecular configurations of poly-L-glutamic acid in water-dioxane solution", <u>Journal of Polymer Science</u> , Vol. XXIII, pp. 851-860.
	Dubin, P.L., et al., 1970, "Hydrophobic bonding in alternating copolymers of maleic acid and alkyl vinyl ethers," <u>J. Phys. Chem.</u> , Vol. 74, No. 14, pp. 2842-2847.
	Eccleston M.E., et al., 1999, "Synthetic routes to responsive polymers: co-polycondensation of tri-functional amino acids with diacylchlorides," <u>Reactive and Functional Polymers</u> , Vol. 42, pp. 147-161.
	Eccleston, M.E. et al., 2000, "pH-Responsive Pseudo-Peptides for Cell Membrane Disruption," <u>J. Controlled Release</u> , Vol. 69, p. 297-307.
	Eccleston, M.E. et al., 2004, "Optical characteristics of responsive biopolymers; co-polycondensation of tri-functional amino acids and Cy-3 bis-amine with diacylchlorides", <u>Polymer</u> , Vol. 45, pp. 25-32.
	Fenyo, J.C., et al., 1979, "Polyelectrolytes conformational probes: Auramine O and ethidium bromide interactions with hypercoiling maleic acid-olefin copolymers", <u>J. Polym. Sci., Polym. Chem. Ed.</u> , Vol. 17, No. 12, pp. 4069-4080.
	Fiordeliso, J., et al., 1994, "Design, synthesis, and preliminary characterization of tyrosine-containing polyarylates: new biomaterials for medical applications," <u>J. Biomater. Sci. Polymer Edn.</u> , Vol. 5, No. 6, pp. 497-510.
	Gautier, S., et al., 1999, "Alkylated poly(L-lysine citramide) as models to investigate the ability of amphiphilic macromolecular drug carriers to physically entrop lipophilic compounds in aqueous media", <u>Journal of Controlled Release</u> , Vol. 60, pp. 235-247.

*Examiner

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)

